From: 02/09/2009 16:09 #279 P.009/013

Remarks:

The above amendments and these remarks are responsive to the final Office

Action dated December 10, 2008, and are being filed for expedited review as a

response after final under 37 C.F.R. § 1.116. Claims 1, 3-7, 9-15, 46-48, and 53-57 are

pending in the application, prior to entry of the present amendments to the claims. In the

Office Action, the Examiner rejected all of the pending claims. Claims 1, 3-7, 9-15,

46-48, 53, and 54 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S.

Patent No. 5,894,841 to Voges ("Voges"). The other pending claims, namely, claims

55-57, were rejected under 35 U.S.C. § 103(a) as being unpatentable over Voges in

view of U.S. Patent No. 6,886,557 to Childers et al. ("Childers").

Applicants traverse the rejections, contending that all of the pending claims are

patentable over the cited references, taken alone or in combination. Nevertheless, to

expedite the issuance of a patent, and to more particularly point out and distinctly claim

aspects of the invention that Applicants want to patent now, Applicants have amended

claims 1, 14, 15, and 53-57, and have added one new claim, namely, claim 58.

However, Applicants reserve the right to pursue any of the amended claims at a later

time. Applicants also have presented remarks showing that all of the pending claims are

patentable over the cited references, taken alone or in combination. Accordingly, in view

of the amendments above and the remarks below, Applicants respectfully request

reconsideration of the application and prompt issuance of a Notice of Allowance

covering all of the pending claims.

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I. Amendments to the Claims

The present communication amends claims 1, 14, 15, and 53-57, and adds new claim 58. Each of the amendments to the claims is supported by the application. Exemplary support (or an explanation) for each amendment is provided, without limitation, in the following table:

Claim(s)	Exemplary Support (or Explanation)
1 (Independent)	Page 3, lines 24-28;
	Page 4, lines 24 and 25;
	Page 9, lines 10-16;
	Page 17, line 5, to page 18, line 21;
	Figure 9
14, 15, and 53-57	(Address formal matters created by the amendments to claim 1)
58 (New)	Page 18, lines 8-18;
	Figure 9

II. Claim Rejections - 35 U.S.C. §§ 102 and 103

The Examiner rejected claim 1 under 35 U.S.C. § 102(b) as being anticipated by Voges. Applicants traverse the rejection, contending that claim 1 is patentable over Voges alone or in combination with Childers. Nevertheless, for the reasons set forth above, Applicants have amended independent claim 1.

Independent claim 1, as currently amended, reads as follow:

1. (Currently Amended) A method of dispensing one or more medicaments, comprising:

providing a treatment plan having at least two rates of action for one or more medicaments;

selecting a different droplet size corresponding to each of the at least two rates of action; and

ejecting medicament droplets having each different droplet size <u>from an ejection apparatus</u> into a respiratory system of a subject according to the treatment plan, thereby allowing the one or more medicaments to act at two or more rates,

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> wherein ejecting medicament droplets includes ejecting droplets that include a bioactive agent in each of a pair of doses requested by the subject, wherein the pair of doses has an elapsed time between the doses,

> and wherein a droplet size of the droplets including the bioactive agent ejected in a later dose of the pair of doses is selected by the ejection

apparatus based on the elapsed time.

Voges and Childers, taken alone or in combination, do not disclose or suggest every

element of currently amended claim 1. For example, the cited references do not

disclose or suggest selection of a droplet size based on the elapsed time between a pair

of doses requested by a subject.

Voges relates to a dispenser for self-administration of physiologically active

substances by inhalation. The reference discloses use of droplet ejection orifices having

different diameters to permit the particle size of an active agent sprayed from the device

to be varied from one time interval to another. See Voges, col. 4, lines 53-58.

However, Voges does not disclose or suggest any treatment strategy or rationale

for changing the particle size of the active agent from one time interval to another, For

example, Voges does not disclose or suggest whether the particle size of the active

agent should be varied from one time interval to another within the same dose, such as

by alternately dispensing larger particles and smaller particles within a single dose, or

should be varied among doses of the active agent. Therefore, Voges particularly does

not disclose or suggest "wherein a droplet size of the droplets including the bioactive

agent ejected in a later dose of the pair of doses is selected by the ejection apparatus

based on the elapsed time" between the pair of doses, as recited in currently amended

claim 1.

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Childers relates to an inhalation device and method for delivering variable

amounts of different components. However, Childers does not disclose or suggest

ejecting droplets of different size. Thus, Childers, like Voges, particularly does not

disclose or suggest "wherein a droplet size of the droplets including the bioactive agent

ejected in a later dose of the pair of doses is selected by the ejection apparatus based

on the elapsed time" between the pair of doses, as recited in currently amended claim

1. Therefore, Childers does not cure the defect in Voges.

In summary, independent claim 1 is patentable over Voges and Childers because

these references do not disclose or suggest every element of claim 1. Claim 1 thus

should be allowed. In addition, claims 3-7, 9-15, 46-48, and 53-58, which depend from

claim 1, also should be allowed for at least the same reasons as claim 1.

New claim 58 further distinguishes claim 1 from the cited reference. Claim 58

recites "wherein ejecting medicament droplets includes ejecting relatively larger and

relatively smaller droplets each including the bioactive agent, and wherein the larger

droplets are selected for ejection in the later dose only if the elapsed time is above a

threshold." The cited references, taken alone or in combination, do not disclose or

suggest selection of relatively larger droplets according to claim 58. Therefore, claim 58

should be allowed not only for depending from claim 1 but also for at least this

additional reason.

III. Conclusion

Applicants submit that this application is now in condition for allowance, in view

of the above amendments and remarks. Accordingly, Applicants respectfully request

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that the Examiner issue a Notice of Allowance covering all of the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

The Commissioner is hereby authorized to charge or credit any deficiencies or over-payments to Deposit Account No. 08-2025 which may be required in connection with this filing.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to Examiner James M. Robinson, Group Art Unit, 3772, Assistant Commissioner for Patents, at facsimile number (571) 273-8300 on February 9, 2009.

Theresa Belland

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